

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA010008-01)

Release Date: 20/08/2024

Re-test Date: 19/08/2027

## Amitriptyline Hydrochloride Related Compound B

### Identification

**Chemical Name :**

5-[3-(Dimethylamino)propyl]-10,11-dihydro-5H-dibenzo[a,d][7]annulen-5-ol (as per EP) ; 5-[3-(dimethylamino)propyl]-10,11-dihydro-5H-dibenzo[a,d]-cyclohepten-5-ol (as per USP)

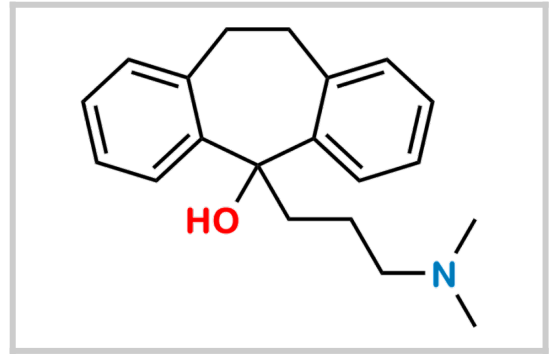
**Alt. Name** : Amitriptynol (USP) ; Amitriptyline  
USP Related Compound B

**CAT No.** : KMA010008

**CAS No.** : 1159-03-1

**Molecular Formula** : C<sub>20</sub>H<sub>25</sub>NO

**Molecular Weight** : 295.4



### Analytical Information

**Batch No.** : KMPS/AMI/B/010

**Description** : Off White Solid

**HPLC Purity** : 97.98 %

**Weight Loss By TGA** : 3.01 %

**% Potency** : 95.03 %

**Solubility** : Acetonitrile

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H NMR** : Confirm

### Additional Information

**Long Term Storage** : Store at 2-8 deg. C for long term storage

**Shipping Condition** : Product is stable to be Shipped at Room Temperature

**% Potency** = [100 - 3.01(Weight Loss By TGA)] x [97.98(HPLC Purity)]/100 = 95.03 %

-Re-tested on 20.08.2024

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		31/12/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		31/12/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA